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Proposed Maximum Residue Limit

PMRL2014-28

Cyprodinil

(publié aussi en français)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the amendment of the preharvest interval for the use on apples to the product label of Vangard 75WG Fungicide Agricultural, containing technical grade cyprodinil, is acceptable. The specific uses approved in Canada are detailed on the label of Vangard 75WG Fungicide Agricultural, *Pest Control Products Act* Registration Number 25509. Furthermore, PMRA has granted full registration to a new end-use product, containing technical grade cyprodinil and difenoconazole, for the control of broad-spectrum diseases on pome fruit. The specific uses approved in Canada are detailed on the product label of Inspire Super Fungicide, *Pest Control Products Act* Registration Number 30827.

The evaluation of these cyprodinil applications indicated that the end-use products have merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for cyprodinil is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I. Existing MRLs for difenoconazole are adequate to cover all uses of Inspire Super Fungicide.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for cyprodinil, are as follows.

Table 1 Proposed Maximum Residue Limits for Cyprodinil

Common Name	Residue Definition	MRL (ppm)¹	Food Commodity
Cyprodinil	4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine	1.7	Pome fruits (Crop Group 11-09) ²
	4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, including the metabolite phenol, 4-[(cyclopropyl-6-methyl-2-pyrimidinyl)amino]-	0.02	Fat, meat and meat byproducts of cattle, goats, hogs, horses, and sheep, milk

¹ ppm = parts per million

² MRL replaces the previously established 0.1 ppm MRL for Pome fruit to accommodate a reduction in the preharvest interval and add MRLs for the remaining commodities in the revised Crop Group 11-09.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Refer to Table 2 for a comparison, where different, of the Canadian MRLs, American tolerances and Codex MRLs for cyprodinil. The proposed Canadian MRL for Crop Group 11-09 (pome fruits) is identical to the American tolerance established for pome fruit (Crop Group 11-10), but is different from the Codex MRLs for apple and pear. There is no Codex MRL established for the pome fruit crop group. The proposed Canadian MRLs for meat byproducts are the same as the corresponding tolerances established in the United States (tolerances listed in 40 CFR Part 180 by pesticide). However, there are no tolerances established in the United States for the fat

and meat of livestock or in milk. The Codex MRL¹ (Codex MRLs searchable by pesticide or commodity) for meat is for mammals other than marine. There are no Codex MRLs established in the fat and meat byproducts of livestock. The proposed Canadian MRL for milk is different from the established Codex MRL.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Pome fruits	1.7 (Crop Group 11-09)	1.7 (Crop Group 11-10)	0.05 (Apple); 1 (Pear)
Fat of cattle, goats, hogs, horses and sheep	0.02	No tolerance established	No MRL established
Meat of cattle, goats, hogs, horses and sheep	0.02	No tolerance established	0.02 (Meat from Mammals other than Marine)
Meat byproducts of cattle, goats, hogs, horses and sheep	0.02	0.02 (Cattle, goats, horses and sheep)	No MRL established
Milk	0.02	No tolerance established	0.0004

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for cyprodinil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

¹ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data from field trials conducted in the United States were submitted to support the amendment of the preharvest interval for apples on the Vangard 75 WG Fungicide Agricultural label and to support the new end-use product Inspire Super Fungicide for use on pome fruits. Cyprodinil was applied to apples and pears at exaggerated rates, and harvested according to label directions. In addition, an apple processing study was reassessed to determine the potential for concentration of cyprodinil into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for cyprodinil was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for pome fruits.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	Preharvest Interval (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Apple	Foliar broadcast spray application/ 1.4	0	0.17	1.4	Not applicable
Pear	Foliar broadcast spray application/ 1.4	0	0.11	0.73	Not applicable

Based on the dietary burden and residue data, an MRL of 0.02 ppm in each of the fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep, and milk to cover the combined residues of cyprodinil and the metabolite CGA-304075 are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of cyprodinil. Residues of cyprodinil in these crop and livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.